

Appl. No. 09/800,070
Reply to Final Office Action mailed March 26, 2003

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BBL No.: 113961-023

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This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-35 (Cancelled)

37. (Currently Amended) A self-supported fibrin material comprising an elongated structure ~~having at least a portion stretched in at least one longitudinal stretching direction,~~ wherein the self-supported fibrin material is stretched along a longitudinal axis.

38. (Currently Amended) The self-supported fibrin material of claim 37, wherein the structure is made of a material selected from the group consisting of fibrin, fibrinogen, chondroitin-4, sulfate, dermatan sulfate, keratan sulfate, hyaluronic acid, chitosan, chitin, alginate, laminin, elastin, fibronectin, collagen, organic polymer, peptide, derivatives thereof, and mixtures thereof.

39. (Currently Amended) The self-supported fibrin material of claim 37, wherein the stretched portion of the structure is porous.

40. (Currently Amended) The self-supported fibrin material of claim 37, wherein the material of the stretched portion of the structure has at least two densities which are different from each other.

41. (Currently Amended) The self-supported fibrin material of claim 40, wherein the first density is at least 1.5 times greater than the second density.

42. (Currently Amended) The self-supported fibrin material of claim 40, wherein the first density is at least 2 times greater than the second density.

43. (Currently Amended) The self-supported fibrin material of claim 40, wherein the first density is at least 5 times greater than the second density.

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44. (Currently Amended) The self-supported fibrin material of claim 37, wherein the elongated structure has a shape selected from the group consisting of thread, tube, hollow profile, film, fleece, sponge and membrane.

45. (Currently Amended) The self-supported fibrin material of claim 37, wherein the stretched portion has a shape selected from the group consisting of thread and tube; said stretched portion having an outer diameter of less than 10 mm.

46. (Currently Amended) The self-supported fibrin material of claim 37, wherein the stretched portion has a shape selected from the group consisting of thread and tube, said stretched portion having an outer diameter of less than 3 mm.

47. (Currently Amended) The self-supported fibrin material of claim 37, wherein the stretched portion has a shape selected from the group consisting of thread and tube, said stretched portion having an outer diameter of between 100 μm and 2500 μm .

48. (Currently Amended) The self-supported fibrin material of claim 37, wherein the stretched portion has a shape of a tube with a central channel substantially parallel to the stretching direction, said central channel having a cross-section perpendicular to the stretched direction with a diameter of less than 15 mm.

49. (Currently Amended) The self-supported fibrin material of claim 37, wherein the stretched portion has a shape of a tube with a central channel substantially parallel to the stretching direction, said central channel having a cross-section perpendicular to the stretched direction with a diameter of less than 10 mm.

50. (Currently Amended) The self-supported fibrin material of claim 37, wherein the stretched portion has a shape of a tube with a central channel substantially parallel to the stretching direction, said central channel having a cross-section perpendicular to the stretched direction with a diameter of less than 5 mm.

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51. (Currently Amended) The self-supported fibrin material of claim 37, wherein the stretched portion has a shape of a tube with a central channel substantially parallel to the stretching direction, said central channel having a cross-section perpendicular to the stretched direction with a diameter between 100 μm and 2500 μm .

52. (Currently Amended) The self-supported fibrin material of claim 48, wherein said tube has a wall thickness between 0.1 mm and 5 mm.

53. (Currently Amended) The self-supported fibrin material of claim 48, wherein said tube has a wall thickness between 0.25 mm and 2.5 mm.

54. (Currently Amended) The self-supported fibrin material of claim 48, wherein said tube has a wall thickness between 0.5 mm and 2 mm.

55. (Currently Amended) The self-supported fibrin material of claim 37, wherein the amount of fibrin in the material is more than 50%.

56. (Currently Amended) The self-supported fibrin material of claim 37, wherein the elongated structure contains fibrin that is at least partially cross-linked.

57. (Currently Amended) A process for the preparation of a self-supported fibrin material, comprising the steps of:

providing a first component of a fibrinogen containing material;

providing a second component of a substance having a capability to convert

fibrinogen into fibrin;

forming a fibrinogen containing material by mixing the first component and the second component; and

subjecting the self-supported fibrin containing material to stretching in a longitudinal direction to obtain an elongated fibrin material along a longitudinal axis of the self-supported fibrin containing material.

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58. (Original) A process according to claim 57 wherein the first component is selected from the group consisting of fibrin, fibrinogen, chondroitin-4 sulfate, dermatan sulfate, keratan sulfate, hyaluronic acid, chitosan, chitin, alginate, laminin, elastin, fibronectin, collagen, organic polymer, peptide, derivatives thereof, and mixtures thereof.

59. (Currently Amended) A process according to claim 57 wherein the stretching is sufficient to extend the length of the self-supported fibrin containing material at least 5%.

60. (Currently Amended) A process according to claim 57 wherein the stretching is sufficient to extend the length of the self-supported fibrin containing material at least 10%.

61. (Currently Amended) A process according to claim 57 wherein the stretching is sufficient to extend the length of the self-supported fibrin containing material at least 25%.

62. (Original) A process according to claim 57, further comprising a drying step.

63. (Currently Amended) A process according to claim 57, wherein at least part of the self-supported fibrin containing material is stretched by mechanical or physical treatment.

64. (Original) A process according to claim 63, wherein the mechanical treatment is one of a compression or an extrusion and the physical treatment is one of an energy treatment or freeze-drying.

65. (Original) A process according to claim 57, wherein the self-supported fibrin containing material is prepared in a mold or in dies, said material being thereafter stretched by a mechanical or physical treatment in said mold or dies.

66. (Original) A process according to claim 57, wherein the self-supported fibrin containing material is at least partially stretched in a solution containing a cross-linking agent.

67. (Original) A process according to claim 57, wherein the self-supported fibrin containing material is mechanically or physically treated in dies or in a mold so as to obtain an

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article having a shape selected from the group consisting of thread, tube, hollow profile, film, fleece, sponge and membrane.

68. (Original) A process according to claim 57, wherein the self-supported fibrin containing material contains free water, and in which at least part of the free water is removed before the mechanical or physical treatment step.

69. (Original) A process according to claim 57, wherein the fibrinogen containing material contains at least a further compound selected from the group consisting of fibrin, chondroitin-4 sulfate, dermatan sulfate, keratan sulfate, hyaluronic acid, chitosan, chitin, alginate, laminin, elastin, fibronectin, collagen, organic polymer, peptide, derivatives thereof, and mixtures thereof.

70. (Original) A process according to claim 57, wherein the self-supported fibrin containing material is prepared from a fibrinogen-containing material as the first component and a solution containing less than 10 IU/ml thrombin as the second component.

71. (Original) A process according to claim 57, wherein the self-supported fibrin containing material is prepared from a fibrinogen-containing material as the first component and a solution containing less than 1 IU/ml thrombin as the second component.

72. (Original) A process according to claim 57, wherein the self-supported fibrin containing material is prepared from solution having a fibrinogen content of at least 3 mg/ml.

73. (Original) A process according to claim 57, wherein the self-supported fibrin containing material is prepared from solution having a fibrinogen content of at least 5 mg/ml.

74. (Original) A process according to claim 57, wherein the self-supported fibrin containing material is prepared from solution having a fibrinogen content of at least 10 mg/ml.

75. (Original) A process according to claim 57, wherein the self-supported fibrin containing material is prepared from a fibrinogen-containing solution containing a calcium complexing agent.

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76. (Original) A process according to claim 57, wherein the material from which the structure is made further contains at least an additive selected from the group consisting of protein, genetic material, anticoagulant, inorganic compound, growth factor, cells, anti-inflammatory compound, compound reducing graft rejection, cell growth inhibitor, antibiotic, antiseptic, analgesic, antineoplastic, chemotherapeutic, polypeptide, protease inhibitor, vitamin, cytokine, cytotoxin, interferon, hormone, antibody, antimicrobial agent, agent for improving the biocompatibility, derivatives thereof, and mixtures thereof.

77. (Original) A process according to claim 57, wherein the self-supported fibrin containing material is submitted to lyophilization after stretching.

78. (Currently Amended) An self-supported fibrin article made at least partly from fibrinogen comprising an elongated structure selected from the group consisting of fibrin containing thread, tube, hollow profile, film, fleece, sponge and membrane, wherein the self-supported fibrin article is stretched along a longitudinal axis.

79. (Original) A thread, tube, hollow profile, film, fleece, sponge or membrane obtainable by a process according to claim 57.

80. (Original) The thread, tube, hollow profile, film, fleece, sponge or membrane of claim 79 wherein the stretched portion is stretched in at least two directions substantially perpendicular to one another.

81. (Original) The thread, tube, hollow profile, film, fleece, sponge or membrane of claim 79, which is rolled around an axis substantially perpendicular to the longitudinal direction.

82. (Currently Amended) A process for the manufacture of a shaped article made at least partly of a self-supported fibrin of claim 37, comprising the steps of:
providing an aqueous fibrinogen-containing solution as a first component;
providing thrombin in an inactive form as a second component; and

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providing an amount of water in the solution such that after mixing the first and second component to form a gel, substantially no water can be removed when submitting the gel to a centrifugation of 1,000 rounds per minute.

83. (Original) The process of claim 82, wherein the thrombin present in the solution is at least partly activated when submitting the solution to a mechanical or physical treatment, advantageously in a mold or in dies.

84. (Currently Amended) A process for making a shaped article made at least partly of a self-supported fibrin of claim 37, comprising the steps of:

- mixing substances containing particles selected from the group consisting of fibrinogen, inactive thrombin, derivatives thereof and mixtures thereof;
- subjecting the mixture to a mechanical or physical treatment, in a mold or in dies;
- wetting or moistening the particles; and
- partially activating thrombin to obtain a shaped article.